Paper No. 26

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte THOMAS G. STOLL
and
KARL P. SCHMIDT

Appeal No. 2005-0601
Application No. 09/489,982

ON BRIEF

Before FRANKFORT, NASE, and MacDONALD, Administrative Patent Judges.
NASE, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal from the examiner's rejection of claims 1 to 21, which are all of the claims pending in this application.[1]

We REVERSE.

[1] Claim 14 was amended subsequent to the final rejection and claim 21 was added subsequent to the final rejection.

BACKGROUND

The appellants' invention relates to a digital prescription carrier and monitor system. A copy of the claims under appeal is set forth in the appendix to the appellants' brief.

The prior art references of record relied upon by the examiner in rejecting the appealed claims are:

Gombrich et al. (Gombrich)	4,835,372	May 30, 1989
Leigh-Spencer et al. (Leigh-Spencer)	5,602,802	Feb. 11, 1997
Goetz	6,397,190	May 28, 2002

For the Record Protecting Electronic Health Information; National Academy Press; 1997 (FRPEHI)

The two rejections under 35 U.S.C. § 103 before us in this appeal are as follows:

1. Claims 1 to 21 as being unpatentable over Gombrich in view of Leigh-Spencer and FRPEHI; and

2. Claims 1 to 21 as being unpatentable over Goetz in view of FRPEHI.

Rather than reiterate the conflicting viewpoints advanced by the examiner and the appellants regarding the above-noted rejections, we make reference to the answer

(mailed July 7, 2004) for the examiner's complete reasoning in support of the rejections, and to the brief (filed January 26, 2004) for the appellants' arguments thereagainst.

OPINION

In reaching our decision in this appeal, we have given careful consideration to the appellants' specification and claims, to the applied prior art references[2], and to the respective positions articulated by the appellants and the examiner. Upon evaluation of all the evidence before us, it is our conclusion that the evidence adduced by the examiner is insufficient to establish a prima facie case of obviousness with respect to the claims under appeal. Accordingly, we will not sustain the examiner's rejection of claims 1 to 21 under 35 U.S.C. § 103. Our reasoning for this determination follows.

In rejecting claims under 35 U.S.C. § 103, the examiner bears the initial burden of presenting a prima facie case of obviousness. See In re Rijckaert, 9 F.3d 1531, 1532, 28 USPQ2d 1955, 1956 (Fed. Cir. 1993). A prima facie case of obviousness is established by presenting evidence that would have led one of ordinary skill in the art to combine the relevant teachings of the references to arrive at the claimed invention.

[2] The appellants have filed affidavits under 37 CFR § 1.131 attempting to remove Goetz as prior art. In view of our decision infra, there is no need for us to resolve the prior art status of Goetz.

See In re Fine, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988) and In re Lintner, 458 F.2d 1013, 1016, 173 USPQ 560, 562 (CCPA 1972).

The claimed subject matter

Claims 1, 7 and 4, the independent claims under appeal, read as follows:

1. A method for conveying a prescribed medication to a patient, the method comprising the steps of:
providing a digital prescription carrier including a read/write memory and an infrared communication interface;
encrypting prescription data defining a prescription so that the data would be indecipherable without appropriate computer decryption software;
uploading, by a prescriber, the prescription data into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;
transferring said carrier by a patient to a pharmacy;
downloading said prescription data from said carrier through said interface at said pharmacy;
decrypting said prescription data from indecipherable form into a form that would be decipherable; and
filling said prescription at said pharmacy; wherein,
the uploading and downloading steps are each accomplished by a data transfer that occurs without physic contact.

7. A method for conveying a prescribed medication to a patient, the method comprising the steps of:
providing a digital prescription carrier including a read/write memory and a communication interface;
entering a first access code into said carrier to enable software access thereto;
uploading prescription data defining a prescription, said data being in a wholly intangible digital form, into said carrier through said interface, said prescription calling for the use of a selected medication of a selected dosage on a selected schedule;

encrypting said prescription data so that said data would be indecipherable without appropriate computer decryption software;

transferring said carrier by a patient to a pharmacy;

entering a second access code in said carrier to enable software access thereto;

downloading said prescription data, said data being in a wholly intangible digital form, from said carrier through said interface at said pharmacy;

decrypting the prescription data to convert the data into an intelligible form; and

filling said prescription by said pharmacist.

14. A digital prescription carrier apparatus comprising:

a carrier housing;

a central processing unit (CPU) positioned within said housing;

a display device positioned on said housing, interfaced to said CPU, and capable of displaying alphanumeric characters;

input/output (I/O)-interface circuitry-positioned-in-said-housing and interfaced to said CPU, said I/O circuitry being capable of interfacing said CPU to an external computer to exchange data therewith;

data memory circuitry positioned within said housing;

encrypting software for scrambling prescription data that represents a prescription into a form that is unintelligible and unreadable, said encrypting software further capable of converting encrypted prescription data to a readable form; and,

prescription software stored in said memory to be processed by said CPU, wherein,

the CPU and the I/O circuitry cooperate to enable uploading, by a prescriber, of the prescription data into said memory circuitry, and downloading of said prescription data at a pharmacy.

The applied prior art

Gombrich

Gombrich's invention relates to a patient identification system for relating items with patients and ensuring that an identified item corresponds to an identified patient.

The patient identification system includes a computer system 42 interconnected to a plurality of remote terminals 62 by conventional telephone wiring 60, 70. The patient identification system further including a portable bar code reading device 48 including a bar code wand 120, a LCD display 116 and a key pad 114. The portable bar code reading device 48 communicates via RF transmission with an RF/PLC modem 56. Gombrich teaches (column 10, lines 65-67) "the portable bar code reading device 48 might utilize infrared (IR) transmission/reception in place of RF transmission." The bar code reading device 48 is utilized to read a patient's unique bar code 50 on a patient's identification bracelet 52, bar codes 51 on labels 53 attached to various items in the hospital relating the item to a specific patient and bar codes 49 on item labels 47 whereby such items can be automatically correlated to a specific patient and reviews performed at the computer system 42 check to ensure that the item properly corresponds to the identified patient.

With regard to the handling of a prescription, Gombrich teaches (column 14, line 40, to column 17, line 11) that:

> After a physician writes a prescription prescribing a drug treatment for the patient, a secretary or other staff person will access from a terminal 45a a drug data file stored in the computer system 42 to display at the terminal 45a the list of drugs after scanning the patient identifier bar code 51 on the patient's chart. The staff person will then enter each scanned drug's dosage and frequency of administration via the terminal 45b. Many drugs have a standard dosage and quantity. These standard values can be stored in the appropriate drug data file of

the computer system 42 along with the drug such that the dosages, etc. need not be separately entered if the prescription calls for a standard dosage. This enters into the computer system 42 the patient's name, drugs, dosage and times of day they are to be administered. This information is stored in the computer system's memory as a data file correlating the patient and drug information. An example of an embodiment of such a data file layout is diagrammatically illustrated in FIG. 17. It will be appreciated that this data file and/or other data files might include additional drug-related information, such as allergies, etc. The staff person then places a preprinted patient identification bar code label 53 on each of the prescriptions and sends them to the pharmacy for filling.

At the time the pharmacist checks and fills the prescriptions, the pharmacist will scan the patient's identification bar code 51 on the patient's prescription using a bar code reader and will bring up the patient's file at a pharmacy terminal 45c. The pharmacist will check the computer data against the prescription. If the pharmacist does not approve, he will change the prescription or take other appropriate action, such as talking to the responsible doctor. If approved, the pharmacist will then fill the prescription by scanning the drug's identification bar code. He will then scan a bar code in his identification badge indicating his approval. If a bar code identifying the drug is not already on the drug package, the pharmacist will take a pre-coded label and affix it to the drug. This might occur in the case of unit dosages not bar coded by the manufacturer, in which case a sheet of bar codes might be provided which are perforated to the same package size specifications as the package of unit dosages. In the case of unique drugs, such as IV solutions where a pharmacist may combine two or more drugs to form a custom patient IV, a custom bar code might be generated in the pharmacy on its bar code printer 46c and the resulting bar code label affixed to the IV solution. Preferably, the bar code label will list all standard IV information and will also list the names of the ingredient drugs and other pertinent data such as patient's name and rate of delivery (drip rate). If not previously entered, the pharmacist might also manually enter any drug administration guidelines noted by the physician, such as time of day if the drug has no standard times or if the prescription varies from the standard times normally given, although this might be done by the nurse at the nurses' station.

Scanning the drug identifier bar code on the drug package after scanning the patient's bar code will automatically enter and record the drug prescription as being approved for that particular patient and the MAR is updated. Dosage and times per day will be automatically displayed and subsequently printed. However,

it will be appreciated that if the times per day for each drug are not stored in the computer system 42, this information can be manually entered at a terminal. Preferably, such things as known allergies for each patient have been previously entered into the patient's computer record such that any drug allergies for a particular patient will be flagged by the computer system and the pharmacist will be informed at the terminal 45c. Moreover, the computer system 42 might be programmed so as to flag any major drug inconsistencies or contradictions at the pharmacy terminal for pharmacy disposition.

. . .

Upon approving the prescriptions, a medical administration record (MAR) for that patient is printed at the pharmacy and placed in the patient's drug cart drawer. After all drugs for the period, i.e., eight or twenty-four hours, have been entered and placed in the cart, a patient/drug schedule or assignment sheet might be printed for each nurse, giving names of patients, room numbers and drugs to be dispensed by time of day and dosage for each nurse's shift. Additionally, these records and schedule sheets can be printed at any time at the nurses' stations.

If the pharmacist changes any of the drugs prescribed, such as when filling a prescription with a generic drug, the computer system 42 will mark the new drug. When giving a drug so marked, an alert will be received at the bar code reading device 48 unless the nurses and the pharmacist have both previously entered their personal identifier bar codes to approve the new drug on the MAR. A special flag will be placed on the unapproved MAR to identify a larger than recommended normal dosage. Additionally, a similar alert will be received at the bar code reading device 48 if the dosage prescribed exceeds the maximum dosage specified in the computer system's data files and if the pharmacist and the nurse have not previously entered their personal identifier bar codes.

When ready to administer treatment, a nurse will take the portable RF bar code reading device 48 and read her own identifying bar code badge to access the system and to identify herself. Next, the nurse will read the patient identifier bar code on the patient's identification bracelet and the item identifier bar code on the items to be administered and press a "SEND" key on the bar code reading device 48 while in the patient's room. This activates the transmission of data via the telephone wiring to the computer system 42. While checking a drug

against the patient's computer stored data files to verify it properly corresponds to the patient, the bar code reading device 48 will preferably light the amber status light 122b to indicate "in progress" or the words "IN PROGRESS" will be displayed on the liquid crystal display 116 of the bar code reading device 48. In certain instances, it may be necessary for the nurse to use the key pad 114 to enter dosages by use of the "DOS" key, such as in the case of custom made IV solutions or when the dose is other than a unit dose. The bar code reading device 48 might include an optional temperature, pulse and blood pressure cuff module, enabling temperature, pulse and blood pressure data to be directly obtained; however, the nurse can also enter the patient's vital signs via the key pad 114 on the bar code reading device 48. Preferably, the bar code reading device 48 will store and will display upon request six to ten previously entered vital statistics by use of the recall key "REC". This enables a new nurse coming on duty or a physician to access the system when in the patient's room and review on the liquid crystal display 116 the more recent vital signs. Additionally, the bar code reading device will preferably store a record of the most recently administered PRN or other controlled drug administered to control pain or the like and the times they were administered. This eliminates the need to track down the patient's records, which is an important benefit in times of emergency. In addition, scrolling keys might be provided to enable scrolling of the data.

The bar code reading device 48 will preferably include a printer module enabling labels to be printed bedside at a label printer 46e interconnected to the portable bar code reading device 48 such that a nurse can print bar code identifier labels as necessary; for example, a nurse might print a label for attachment to a test tube containing a patient's blood sample by scanning the patient's identification bar code and pressing a print key on the portable bar code reader 48.

If the drug bar code scanned matches the patient identification bar code and the pharmacy-entered drug code, the green status light 122c or other appropriate readout on the LCD 116 will prompt the nurse to proceed. If there is a discrepancy, the red status light 122a might flash and/or some other appropriate readout might appear at the LCD display 116 indicating why the red status light 122a is on. The nurse may elect to override the warning at that time if she believes it is appropriate to administer the drug or take whatever actions she deems necessary. In such cases, a computer record of such events will be stored and will be available for review at a future time.

Leigh-Spencer

Leigh-Spencer's invention relates to a medication reminder system, apparatus and method for notifying patients of the correct times during the day for taking a medicine. A programming station 10 and portable module 12 are shown in Figures 1-5. The programming station 10 is provided with a body 14 with front panel 16 having a display 18 and keypad 20. The front panel 16 is also provided with a receptacle 30 for receiving the module 12 in order to program the module 12 through the station 10. The module 12 is provided with a body 32 having a cover 31 with push button 34, light emitting diode (LED) 36, sound port 38 and hole 40. The hole 40 is used to facilitate attachment of the module 12 to a separate article which is regularly carried by the patient, for example, a key ring. A communication link between the module 12 and station 10 is through LED 36 on the body 32 and an LED 44 within receptacle 30. Other communication links may be used between the module 12 and station 10 such as, but not being limited to, optical, fibre-optic, acoustic, magnetic, capacitative, radio frequency, magnetic/capacitative, or electrical data transfer links.

In operation, the programming station 10 is located at a central dispensary, for example with a pharmacist. The pharmacist, when filling a patient's prescription and completing the written instructions would initiate programming of the module 12 with medication data. When the module 12 is module is away from the station 10, the LED

36 provides a flashing visual alarm and the sound port 38 provides an auditory alarm warning a patient that it is time to take the prescribed medicine. Both alarms are silenced by push button 34.

FRPEHI

FRPEHI teaches in a health care information system, encrypting chunks of information (components of the patient record, including text, laboratory results, and images) by a server through software when the information is transmitted over a network such as the Internet, and then decrypting the chunks of information by special access software to allow viewing of the information, wherein the software is designed to only allow accessing and viewing of the information by receipt of properly authenticated user credentials (pp. 86-89, 106-108, 120-122).

Goetz

Goetz's invention relates to a veterinary medical information product which is maintained and controlled by the handler or owner of the animal to which the information pertains. The veterinary medication management system 10 includes two or three separate components to assist the handler/owner control, monitor and manage administration of prescribed medications to an animal patient. The system comprises a handler/owner component 12 having a retrievable animal and handler/owner database

of animal medical history, prior prescribed medications and current prescribed medications, and it includes a data transfer interface, e.g., a hardwired interface, such as an RS232 interface or infrared data transfer port. The system also includes a veterinarian component 16 having a retrievable veterinarian's database of medication information and an input/output device enabling a prescribing veterinarian to enter prescription information into the veterinarian component. The veterinarian's database is capable of receiving and storing handler/owner data transferred from the handler/owner component through said data transfer interface. The system finally also includes a veterinarian support component 18 resident on a veterinarian's computer. Goetz teaches that the veterinary component 16 and support component 18 may be combined into one veterinary component as the veterinarian's needs dictate.

The veterinarian's computer is adapted to interface with said handler/owner component to transfer prescription data to said veterinarian support component. The system 10 in accordance with the first embodiment of Goetz's invention uses a smart card 14 to make the link between the components easy, quick, and secure. The components may alternatively communicate via infrared serial communication links, or other communication methods rather than a smart card. At least one of or each of the veterinarian component and the veterinarian support component has the capability of searching a medication database to determine potential medication interactions with

currently prescribed medications and identify those to the veterinarian for selective downloading to the handler/owner component so that the handler/owner can be alerted to the potential interactions.

The handler/owner component has a scheduler which tracks a plurality of medication dose schedules and includes alarm functions to prompt a handler/owner to administer particular medications to the animal, reschedule them, and/or alert the handler/owner to potential interactions between medications and/or provide caution information to the handler/owner for administration of the medication to the animal. Goetz teaches (column 5, lines 22-25) that the handler/owner component "[p]rovides security, via coding features and data encryption, to prevent unauthorized use and access to the data encoded on the smart card or within the handler/owner component."

Rejection 1

We will not sustain the rejection of claims 1 to 21 under 35 U.S.C. § 103 as being unpatentable over Gombrich in view of Leigh-Spencer and FRPEHI.

In our view, a prima facie case of obviousness has not been established since the evidence presented (i.e., Gombrich, Leigh-Spencer and FRPEHI) would not have led one of ordinary skill in the art to combine the relevant teachings of the applied prior

art to arrive at the claimed invention. In that regard, we see no suggestion, teaching, or motivation in the applied prior that it would have been obvious at the time the invention was made to a person having ordinary skill in the art to have modified Gombrich's portable bar code reading device 48 as set forth in the rejection under appeal. At best, the combined teachings of the applied prior art would have suggested (1) adding the portable module of Leigh-Spencer to the system of Gombrich so that the patient upon leaving the hospital would be reminded of the times for taking prescribed medication; and (2) encrypting the medical data of the modified system of Gombrich. However, this does not arrive at the claimed subject matter.

The only possible suggestion for modifying Gombrich so as to arrive at the claimed invention stems from hindsight knowledge derived from the appellants' own disclosure. The use of such hindsight knowledge to support an obviousness rejection under 35 U.S.C. § 103 is, of course, impermissible. See, for example, W. L. Gore and Assocs., Inc. v. Garlock, Inc., 721 F.2d 1540, 1553, 220 USPQ 303, 312-13 (Fed. Cir. 1983), cert. denied, 469 U.S. 851 (1984).

For the reasons set forth above, the decision of the examiner to reject claims 1 to 21 under 35 U.S.C. § 103 as being unpatentable over Gombrich in view of Leigh-Spencer and FRPEHI is reversed.

Rejection 2

We will not sustain the rejection of claims 1 to 21 under 35 U.S.C. § 103 as being unpatentable over Goetz in view of FRPEHI.

In our view, a prima facie case of obviousness has not been established since the evidence presented (i.e., Goetz and FRPEHI) would not have led one of ordinary skill in the art to combine the relevant teachings of the applied prior art to arrive at the claimed invention. In that regard, we see no suggestion, teaching, or motivation in the applied prior that it would have been obvious at the time the invention was made to a person having ordinary skill in the art to have modified Goetz's handler/owner component 12 as set forth in the rejection under appeal. At best, the combined teachings of the applied prior art would have suggested encrypting the medical data on Goetz's handler/owner component 12. However, this does not arrive at the claimed subject matter. The only possible suggestion for modifying Goetz so as to arrive at the claimed invention stems from hindsight knowledge derived from the appellants' own disclosure.

For the reasons set forth above, the decision of the examiner to reject claims 1 to 21 under 35 U.S.C. § 103 as being unpatentable over Goetz in view of FRPEHI is reversed.

CONCLUSION

To summarize, the decision of the examiner to reject claims 1 to 21 under 35 U.S.C. § 103 is reversed.

REVERSED

CHARLES E. FRANKFORT
Administrative Patent Judge

JEFFREY V. NASE
Administrative Patent Judge

ALLEN R. MacDONALD
Administrative Patent Judge

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